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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,350

11/07/2005

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,350	<b>Applicant(s)</b> JINA, ARVIND N	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-52, 91 and 93-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-52, 91 and 93-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/13/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The amendment dated 24 April 2008 has been received.
2. Claims 1-39 and 53-90 have been cancelled.
3. Claims 93-95 have been added. Claims 40-52 and 91-95 are pending.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 93 and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 93 is vague with respect to the recitation of "the subsystem" of claim 40 because it lacks antecedent support in claim 40.

Claim 95 is confusing with respect to the recitation of the use of a "door" that has not previously been recited or described. There is this door disposed?

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1641

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 40-52, 91 and 93-94 rejected under 35 U.S.C. 103(a) as being unpatentable over Law (US 6,562,581) in view of Ullman (US 4,857,453) and Zin (US 6,534,324).

Law (6,562,581) discloses a flow-through cell for detecting glycosylated hemoglobin from a blood sample. Law teaches applying an untreated whole blood sample to a sample well, lysing the blood sample with a lysing agent and a buffer, transporting the mixture to a capture zone, binding the glycosylated hemoglobin with a capture agent, adding a developing solution containing a peroxide and a dye to enable detection of the capture glycosylated hemoglobin. See column 8, example 5.

Law differs from the instant claims in failing to teach a membrane comprising an elution area, a sample addition area, a lysing area and a capture area.

However, devices with the above zones are well known and conventional in the art. Ullman, for example, discloses a device comprising a buffer capsule connected to a sample addition area, a labeling zone and one or more immunosorbing capture zones.

See column 22 and figure 1. Ullman teaches that the buffer capsules contain solvent for the sample including detergent, buffers such as borate, phosphate, tris, etc. See column 14, lines 43-68. The capture agents in the immunosorbing zones are specific binding members including antibodies, biotin, avidin, receptors, DNA, etc. See column 6, lines 1-23.

And Zin discloses an assay strip comprising a sample addition zone, a conjugate zone, and buffer zone, a capture zone and an absorbent sink at the end. Zin teaches that the buffer zones carries buffers appropriate for the specific assay and can be adapted to the individual analytes. See column 5, lines 50-65. Buffers include Tris, Tween or PBS.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Ullman, for example, to detect glycated and non-glycated hemoglobin such as taught by Law. The detection of this hemoglobin would necessitate lysis of the blood sample, and at least one of the buffer capsule taught by Ullman would have the obvious choice for the lysing agent taught by Law. The second buffer capsule would have been expected to contain the elution buffer and a skilled artisan would have had a reasonable expectation of success in choosing the appropriate capture agents for glycated and non-glycated hemoglobin since such agents are well known in the art as demonstrated by Law. The reference of Zin demonstrates that it is well known in the test strip art to place buffer zones in various locations along the test strip according to the desired sequence of assay.

With respect to claim 41, Law, Ullman and Zin all teach membranes having capillary functions.

With respect to claim 42, Law teaches lysing agent. And Ullman teaches buffer solution containing detergents capable of lysing RBC. See column 14, lines 65-68.

With respect to claims 43 and 52, Ullman teaches separate buffer capsules containing various buffers. See column 14, lines 34-68.

With respect to claims 44 and 45, Law teaches chemical agents for capturing glycated hemoglobin. See column 2, lines 59-67.

With respect to claims 46-47, Ullman teaches the detection multiple analytes using separate immunosorbing zones. See column 11, lines 43-50.

With respect to claim 48, Law discloses that it is conventional in the art to measure both glycated and non-glycated hemoglobin. See column 2.

With respect to claim 91, Zin discloses a buffer zone disposed downstream of the sample addition zone.

### *Response to Arguments*

8. Applicant's arguments filed 24 April 2008 have been fully considered but they are not persuasive.

Applicant argues that the cited references fail to teach all of the claim limitations because amended claim 40 requires that an untreated whole blood sample is applied directly to the receiving portion of the membrane and that no pre-treatment of the

sample such as dilution is involved. Applicant argues that Law does not teach this limitation because Law teaches that the whole blood sample is diluted with a lysing agent and a buffer before the mixture is transported to the capture zone.

This argument is not persuasive. Claim 40 recite that after an untreated whole blood sample is added to the membrane, an eluting agent is allowed to contact the whole blood sample. This is the same as disclosed by Law.

Law specifically teaches a cassette comprising a sample addition area, a lysing agent holding area, and a capture zone. Law teaches that whole blood sample is deposited into the sample well; thereafter the sample is treated with a lysing agent and a buffer before being transported to the capture zone. See column 8, lines 22-26. Clearly, Law teaches that the whole blood sample added to the sample addition area is *untreated*.

The argument that Law differs from the instant claims because Law teaches the application of a *diluted* whole blood sample is not persuasive. The dilution of the sample does not occur until after the sample has been added to the device. The device doesn't specifically teach a membrane, however, the membrane is taught by Ullman and Zin.

The argument that Zin and Ullman do not teach applying a whole blood sample to the receiving portion of a membrane is not persuasive. This limitation is taught by Law in view of Zin and Ullman.

*Conclusion*

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
July 15, 2008